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| APPLICATION NO.                      | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO |
|--------------------------------------|-------------|----------------------|-------------------------|-----------------|
| 09/830,343                           | 11/23/2001  | Karen Akinsanya      | 033236/0114             | 6930            |
| 7590 09/29/2004                      |             |                      | EXAMINER                |                 |
| Stephen A Bent                       |             |                      | DEBERRY, REGINA M       |                 |
| Foley & Lardner<br>Washingto Harbour |             |                      | ART UNIT                | PAPER NUMBER    |
| 3000 K Street NW Suite 500           |             |                      | 1647                    |                 |
| Washington, DC 20007-5109            |             |                      | DATE MAILED: 09/29/2004 |                 |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   | Application No.   | Applicant(s)   |  |  |  |  |
|---|---|--|--|--|--|--|
|   | 09/830,343  | AKINSANYA ET AL.   |  |  |  |  |
| Office Action Summary   | Examiner  | Art Unit   |  |  |  |  |
|   | Regina M. DeBerry   | 1647   |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address   |   |  |  |  |  |  |
| Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPL THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a repl - If NO period for reply is specified above, the maximum statutory period - Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | 136(a). In no event, however, may a reply be timely within the statutory minimum of thirty (30) days will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE                    | nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133). |  |  |  |  |
| Status  |   |  |  |  |  |  |
| 1) Responsive to communication(s) filed on 20 J   | <u>une 2003</u> .   |  |  |  |  |  |
| 2a) This action is <b>FINAL</b> . 2b) ☐ This  | ·   |  |  |  |  |  |
| ,   | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. |  |  |  |  |  |
| Disposition of Claims   |   |  |  |  |  |  |
| 4) Claim(s) 1-12 is/are pending in the application 4a) Of the above claim(s) is/are withdra 5) Claim(s) is/are allowed. 6) Claim(s) is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) 1-12 are subject to restriction and/or   | wn from consideration.  |  |  |  |  |  |
| Application Papers  |   |  |  |  |  |  |
| 9)☐ The specification is objected to by the Examine   | er.   | •  |  |  |  |  |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.   |   |  |  |  |  |  |
| Applicant may not request that any objection to the   |   |  |  |  |  |  |
| Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Ex   |   |  |  |  |  |  |
| Priority under 35 U.S.C. § 119  |   |  |  |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority document</li> <li>2. Certified copies of the priority document</li> <li>3. Copies of the certified copies of the priority application from the International Burea</li> <li>* See the attached detailed Office action for a list</li> </ul>  | ts have been received.<br>ts have been received in Application<br>ority documents have been receive<br>u (PCT Rule 17.2(a)).  | on No<br>ed in this National Stage   |  |  |  |  |
| Attachment(s)   |   |  |  |  |  |  |
| 1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)   |   |  |  |  |  |  |
| <ul> <li>2) Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)</li> <li>Paper No(s)/Mail Date</li> </ul>  | Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:   | ate latent Application (PTO-152)   |  |  |  |  |

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## **DETAILED ACTION**

## Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-12, drawn to the pharmaceutical composition, method of preparing pharmaceutical composition, method of administering composition.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: species of SEQ ID NO:7.

Applicant is required to elect one species of SEQ ID NO:7. Applicant must elect one amino acid for Xaa1, Xaa2 and Xaa3:

elect one amino acid for Xaa1 (elect either His OR Tyr) and elect one amino acid for Xaa2 (elect either Trp OR Leu) and elect one amino acid for Xaa3 (elect either Tyr OR Arg).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply

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must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner: claims 1, 8 and 11 (SEQ ID NO:7).

The following claim(s) are generic: claims 3, 5, 7, 10, and 12 (SEQ ID NO:6).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species comprise distinct sequences because they are composed of unrelated or diverse sequences, different coding regions and/or imparts structural and functional differences.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, separate search requirements, and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*A*A*M* → RMD 9/17/04

Clyabet C. Hemmeres

ELIZABETH KEMMERER PRIMARY EXAMINER